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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/734,329	11/30/2000	Benoit de Crombrugghe	UTXC:666US/10020509	3826

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EXAMINER	
WHITEMAN, BRIAN A	
ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 09/27/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/734,329	DE CROMBRUGGHE ET AL.	
	Examiner	Art Unit	
	Brian Whiteman	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-77 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-77 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-77 are pending.

Election/Restrictions

Restriction to one of the following inventions is required and an election of species is required under 35 U.S.C. 121:

I. Claims 1-30 and 32-55, drawn to a DNA segment comprising a protein coding region encoding an Osterix polypeptide, classified in class 536, subclass 23.1.

II. Claims 31 and 64-68, drawn to a composition comprising a purified Osterix polypeptide or a recombinant Osterix polypeptide, classified in class 530, subclass 350.

III. Claims 56-63, drawn to a method of treating osteoporosis in a patient using a vector comprising a nucleic acid sequence encoding an Osterix polypeptide, classified in class 514, subclass 44.

IV. Claim 69, drawn to an antibody that is immunologically active with Osterix, classified in class 424, subclass 130.1.

V. Claim 70-74, drawn to a method for identifying an effector of Osterix transcription, classified in class 424, subclass 9.1.

VI. Claims 75-77, drawn to a method for identifying an agent that modulates osteoblasts, classified in class 424, subclass 9.1.

Inventions I and II, IV are distinct because the peptides of Invention II are distinct in chemical structure and function, as well as therapeutic function from the polynucleotide of Invention I; and the antibodies of Invention IV. Inventions are distinct if it can be shown that

they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation and have different functions. Additionally, polynucleotides, peptides, and antibodies can be used in materially distinct methods. For example, the polynucleotides can be used for as detection probes or in a method of DNA therapy, peptides can be used for antigen presenting cell priming or peptide therapy and antibodies can be used in screening assays or antibody therapy. The different between inventions I, II, and IV are further underscored by their different classification and independent search status.

Inventions I and III, V, VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the DNA segment from Invention I can be used in materially different processes as exemplified in groups III, V, and VI. Furthermore, the DNA segment in group I can be used as a probe; naked DNA therapy, or ex vivo gene therapy. The different between inventions I and III, V, and VI are further underscored by their different classification and independent search status.

Inventions II and V, VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP

§ 806.05(h)). In the instant case, the peptide from Invention II can be used in materially different processes as exemplified in groups V and VI. Furthermore, the peptide from group II can be used for producing antibodies to said peptide, or peptide therapy. The different between inventions II and V, VI are further underscored by their different classification and independent search status.

Inventions IV and V, VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the antibody from Invention IV can be used in a screening assay, producing monoclonal antibodies, a diagnostic assay, which are materially different processes from Groups V and VI.

Although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because each of the methods of inventions III, V, and VI constitutes patentably distinct inventions for the following reasons: Each of the inventions is directed to different goals and comprises materially distinct steps, wherein each of the compositions in each invention is structurally distinct and/or generates distinct mechanisms and functional effects as indicated above. The scope of each of the cited inventions encompasses an employed method, which generates distinct function(s) and effect(s), and furthermore does not necessarily overlap with that of another invention. Furthermore, invention III is directed to a DNA therapeutic method, invention V is directed a method for identifying an effector of Osterix transcription; invention VI

is directed to identifying an agent that modulates osteoblasts. Each of the inventions comprises materially distinct steps, and/or generates different functions and effects, and thus, is not required for use with one another. Therefore the invention of group III is distinct from groups V, VI.

If applicants elect group I, a further restriction is required.

Claim 1 is generic to a plurality of disclosed patentably distinct species comprising a trans-activation domain in claim 2, a zinc finger domain in claim 5, a proline rich domain in claim 8. Applicant is further required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

If applicants claim 5 a further election of species is required. Claim 5 is generic to a plurality of disclosed patentably distinct species comprising a transcription factor in claims 12-15. Applicant is further required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claim 32 is generic to a plurality of disclosed patentably distinct species comprising segment comprises a sequence of at least a specified contiguous nucleotides from SEQ ID NO: 1 in claims 33-39 and 47. Applicant is further required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claim 52 is generic to a plurality of disclosed patentably distinct species comprising a viral vector selected from claim 53. Applicant is also required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

If applicants elect group III, a further restriction is required.

This application contains claims directed to the following patentably distinct species of the claimed invention: routes of administration listed in claim 62.

Applicant is further required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 56 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Claim 56 is generic to a plurality of disclosed patentably distinct species comprising a viral vector selected from claim 61. Applicant is also required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Because these inventions are distinct for the reasons given above and the search required for each Group is not required for the other Groups, restriction for examination purposes as indicated is proper.

It would be unduly burdensome for the examiner to search and consider patentability of all of the presently pending claims, a restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 § 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kay Pinkney whose telephone number is (703) 305-3553.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (703) 305-0775. The examiner can normally be reached on Monday through Friday from 8:00 to 5:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's mentor, primary examiner, Dave Nguyen can be reached at (703) 305-2024.
If attempts to reach the primary examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader, SPE - Art Unit 1635, can be reached at (703) 308-0447.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Brian Whiteman
1635
9/26/02

DAVE T. NGUYEN
PRIMARY EXAMINER